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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,092	06/15/2005	Robert Petermann	112701-626	9222

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EXAMINER	
DEES, NIKKI H	
ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
11/20/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/539,092	PETERMANN ET AL.	
	Examiner	Art Unit	
	Nikki H. Dees	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 19, 2008, has been entered.

2. Claims 1-3 and 5-13 are currently pending in the application. Claim 4 has been cancelled. The previous 112 rejection of claim 13 has been withdrawn in view of Applicant's amendment to claim 13. The previous 103 rejection of claims 1, 2, and 7-13 over Mazer in view of WHO has been withdrawn in view of Applicant's amendment to claim 1.

Claim Objections

3. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 12 limits the source

of claim 1 to a source selected form protein, carbohydrate, and lipid. Amended claim 1 requires all of a protein source, a carbohydrate source and a lipid source. As all of the limitations of claim 12 are required in claim 1, claim 12 is not considered further limiting.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 5 is dependent upon claim 4, which has been cancelled. For purposes of examination, claim 5 will be interpreted as being dependent upon claim 1.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-3 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeWille et al. (6,475,539) in view of PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html).

9. DeWille et al. teach a nutritional formula that comprises a protein source, a carbohydrate source, a lipid source, and lactic acid. The formula in its liquid state has a pH of 3.0-4.6 (col. 6 lines 13-47). The solution may be directly acidified. That is, the pH of the solution may be adjusted by the addition of the acid, not fermentation (col. 15 lines 9-34). The nutritional formula may be provided as a ready-to-feed form, concentrate, or powder (col. 10 lines 26-30). Protein sources taught for use in the invention include whey protein and casein. The whey protein is used as a concentrate or isolate, which, as an essentially undenatured protein, is considered to be intact (col. 11 lines 36-50).

10. Regarding claims 7-9, DeWille et al. teach that the formula is prepared by first forming a protein/carbohydrate/oil mixture that is then acidified with an edible acid (col. 20 lines 1-9).

11. Regarding claims 10 and 11, the statements of intended use for the methods are not considered to patentably distinguish over the prior art. DeWille et al. teach preparing acidified nutritional formula by directly adding lactic acid to the nutritional formula (col. 15 lines 9-34). Further, low pH in foodstuffs is known to inhibit microbial growth (col. 6 lines 8-10).

12. Regarding claim 13, the amount of acid in the invention encompasses the range of percentages as claimed by applicants when calculated on a dry weight basis using

claims 1 and 7 of DeWille et al. As DeWille et al. teach lactic acid for use in their invention, and their formula has a pH in the range overlapping the range claimed by Applicant's, it would have been expected that the amount of lactic acid needed to provide a pH as claimed by DeWille et al. would fall within the range claimed by Applicants.

13. DeWille et al. are silent as to their invention comprising L(+) lactic acid and to the formula being an infant formula.

14. Purac teaches the availability of edible L(+) lactic acid solution. The FCC products are indicated to be foodsafe.

15. One of ordinary skill in the art at the time the invention was made, desiring to acidify the invention of DeWille et al. with lactic acid, would have found it obvious to use L(+) lactic acid to provide the acidification. L(+) lactic acid was known in the art for addition to foodstuffs, and lactic acid is specifically taught as an acidulent in the nutritional formula of DeWille et al. Applicant is doing no more than using a known compound for its intended use in order to provide the predictable result of acidifying a foodstuff. Therefore, the combination of DeWille et al. the PURAC products FCC 50, 80 or 88 would have been obvious to one of ordinary skill in the art at the time the invention was made.

16. Regarding the invention of DeWille et al. being an infant formula, one of ordinary skill in the art at the time the invention was made, wishing to provide a complete nutritional product for infants rather than children 13 months and older as taught by DeWille et al. (col. 10 lines 55-59) would have been able to modify the nutritional profile

of DeWille et al. in order to provide a nutritional formula that met the nutritional needs of infants. One of ordinary skill, working from the teachings of DeWille et al., would have found it obvious to provide a shelf stable product that met the nutritional needs of infants. These modifications would not have required undue experimentation, and would have been expected to result in an appropriately acidified infant nutritional formula.

17. Claims 1, 3-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P.; Jenness, Robert; Keeney, Mark; Marth, Elmer H. 1999. Fundamentals of Dairy Chemistry (3rd Edition). (pp. 1, 82-83). Springer – Verlag).

18. Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

19. Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

20. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

21. Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

22. The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

23. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding infants as taught by Schwartz with L (+) – lactic acid as taught by the WHO in order to result in an infant formula with higher acidity for improved digestion.

24. Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

25. Claims 1, 3 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz (Schwartz, A.B. 1926. "The Use of Lactic Acid Milk in Infant Feeding." The American Journal of Nursing. Vol. 26, No. 12. pp. 927-932) in view of PURAC (PURAC. 2001. http://web.archive.org/web/20010411064329/www.purac.com/products/index.html) with additional evidence provided by Wong et al. (Wong, Noble P., Jenness, R., Keeney, M., Marth, E. H. 1999. Fundamentals of Dairy Chemistry. 3rd Edition. pp. 1, 82-83. Springer – Verlag).

26. Schwartz teaches milk acidified with lactic acid for the feeding of infants who are below normal weight. He states that modified milk for the feeding should contain "a proper proportion of fat (lipid), protein and carbohydrate" (p. 927).

27. Schwartz teaches the formula being directly acidified by the addition of USP lactic acid (p. 931).

28. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

29. Schwartz is silent as to the ratio of lactic acid enantiomers present in the composition, as well as the pH of the composition.

30. Purac teaches edible L(+) lactic acid that is in compliance with all major food codices.

31. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the lactic acid nutritional formula for feeding infants as taught by Schwartz with L (+) lactic acid as taught by Purac to result in an infant formula with higher acidity for improved digestion. Applicant is utilizing a known compound, L(+) lactic acid, for its intended use as a food acidulent in order to provide the obvious combination of an acidified infant nutritional formula. This combination is further considered to obvious as there would be no undue experimentation required to utilize the L(+) lactic acid where the addition of lactic acid is specifically taught by Schwartz.

32. Regarding the pH of the nutritional formula, one of ordinary skill in the art at the time the invention was made would have possessed the ability to measure and alter the

pH of the composition as taught by Schwartz by adding more or less lactic acid in order to obtain a final product that was palatable while also achieving the desired effects with the lactic acid.

33. Claims 1, 3 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahata (4,212,893) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives. "Lactic acid and its ammonium, calcium, potassium, and sodium salts." World Health Organization Technical Report Series, 1974, No. 539) with additional evidence provided by Wong et al. (Wong, Noble P., Jenness, R., Keeney, M., Marth, E. H. 1999. Fundamentals of Dairy Chemistry. 3rd Edition. pp. 1, 82-83. Springer – Verlag).

34. Takahata teaches an acidified whole milk beverage comprising whole milk and an organic acid (Abstract). Organic acids taught include lactic acid (col. 2 lines 32-36). The final pH of the beverage taught is within the range of 2.5 to 4.5 (col. 2 lines 25-27).

35. Milk is known to contain proteins, carbohydrates and lipids. The proteins, in particular, comprise whey protein and casein, as shown by Wong et al. in Table 3.1.

36. Takahata is silent as to the enantiomeric ratio of lactic acid present in his composition.

37. The WHO teaches that (DL) – lactic acid and D (-) – lactic acid should not be used in infant foods. This leaves only L (+) – lactic acid for use in infant foods.

38. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized L (+) – lactic acid in the beverage taught by

Takahata in order to result in a beverage that may be marketed to the widest possible audience, including infants.

Response to Arguments

39. Applicant's arguments filed September 19, 2008, have been fully considered but they are not persuasive.

40. The 103 rejection over Mazer et al. in view of WHO has been withdrawn in view of Applicant's amendment to claim 1. Mazer et al. do not teach their nutritional formula comprising a protein source, lipid source and carbohydrate source. A new ground of rejection has been presented *supra* addressing Applicant's amended claim 1.

41. With regard to the 103 rejection of claims 1, 3-6 and 12 over Schwartz in view of WHO, Applicant argues that the combination of references does not teach all of the elements of the rejected claims (Remarks, p. 7). Applicant further argues (Remarks, p. 8) that WHO fails to teach the use of L(+) lactic acid in formula and WHO teaches away from using L(+).

42. The WHO teaches that D-(-) and DL -lactic acid are not appropriate for use in infant formulas. One of ordinary skill would have recognized that L-(+) lactic acid is the obvious choice for inclusion in the infant formula where the direct addition of lactic acid is specifically taught and that the teaching away from the use of DL lactic acid is to

avoid the inclusion of D(-) lactic acid, not the L(+) that is also present in the mixture. L(+) acid is known to be present in mammalian metabolism (WHO, p. 1), providing further motivation to use L(+) lactic acid in foodstuffs intended for human consumption. One of ordinary skill would further recognize that food-grade lactic acid is commonly sold as 95% L(+) as evidenced by PURAC literature and could have utilized the L(+) lactic acid without any undue experimentation to result in the directly acidified formula as taught by Schwartz.

43. With regard to the 103 rejection of claims 1, 3-6 and 12 over Takahata in view of WHO, Applicant again argues that the combination of references does not teach all of the elements of the rejected claims (Remarks, p. 8).

44. The WHO teaches that D-(-) and DL -lactic acid are not appropriate for use in infant formulas. One of ordinary skill would have recognized that L-(+) lactic acid is the obvious choice for inclusion in the infant formula and that the teaching away from the use of DL lactic acid is to avoid the inclusion of D(-) lactic acid, not the L(+) that is also present in the mixture. L(+) acid is known to be present in mammalian metabolism (WHO, p. 1), providing further motivation to use L(+) lactic acid in foodstuffs intended for human consumption. One of ordinary skill would further recognize that food-grade lactic acid is commonly sold as 95% L(+) as evidenced by PURAC literature and could have utilized the L(+) lactic acid without any undue experimentation to result in the acidified formula as taught by Takahata.

Conclusion

45. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Alm (Alm, L. 1982. "Effect of Fermentation on L(+) and D(-) Lactic Acid in Milk" J. Dairy Sci. Vol. 65. pp. 515-520). Column 2 second full paragraph states "Restricted consumption of products containing high D(-) lactic acid is recommended, and in infant nutrition products containing D(-) or DL mixture should be avoided."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nikki H. Dees
Examiner
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/Carol Chaney/
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